

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

THE CITY OF HUNTINGTON,

Plaintiff,

v.

CIVIL ACTION NO. 3:17-01362

AMERISOURCEBERGEN DRUG  
CORPORATION, et al.,

Defendants.

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CABELL COUNTY COMMISSION,

Plaintiff,

v.

CIVIL ACTION NO. 3:17-01665

AMERISOURCEBERGEN DRUG  
CORPORATION, et al.,

Defendants.

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**MEMORANDUM OF LAW IN OPPOSITION TO  
PLAINTIFFS' MOTION TO ADOPT MDL COURT'S AUGUST 19, 2019, ORDER  
REGARDING THE FEDERAL CONTROLLED SUBSTANCES ACT THAT WAS  
ENTERED IN DIFFERENT CASES**

**TABLE OF CONTENTS**

INTRODUCTION .....	1
ARGUMENT .....	2
THE MDL COURT’S ORDER THAT WAS ENTERED IN DIFFERENT CASES IS NOT BINDING IN THIS CASE.....	2
A.    The MDL Order Is Not Law of the Case Because It Was Entered in Different Cases Involving Different Plaintiffs Alleging Different Claims.....	2
B.    Law of the Case Does Not Support Adoption of the MDL Order Because That Order Is Clearly Erroneous and Would Cause Manifest Injustice. ....	12
CONCLUSION.....	20

## TABLE OF AUTHORITIES

<b>Cases</b>	<b>Page(s)</b>
<i>Adesina v. Aladan Corp.</i> , 438 F. Supp. 2d 329 (S.D.N.Y. 2006).....	6, 7
<i>In re Airport Car Rental Antitrust Litig.</i> , 521 F. Supp. 568, 572 (N.D. Cal. 1981) .....	12
<i>Allen v. Am. Capital Ltd.</i> , 287 F. Supp. 3d 763 (D. Ariz. 2017) .....	11
<i>Am. Canoe Ass'n v. Murphy Farms, Inc.</i> , 326 F.3d 505 (4th Cir. 2003) .....	10
<i>Amorin v. Taishan Gypsum Co., Ltd.</i> , 2019 WL 2172707 (E.D. Va. May 20, 2019) .....	6
<i>Askins v. U.S. Dep't of Homeland Sec.</i> , 899 F.3d 1035 (9th Cir. 2018) .....	10
<i>Astra USA, Inc. v. Santa Clara County</i> , 563 U.S. 110 (2011).....	15
<i>Burks v. O'Connor, Kenny Partners, Inc.</i> , 77 F. App'x 351 (6th Cir. 2003) .....	11
<i>Carlson v. Bos. Sci. Corp.</i> , 856 F.3d 320 (4th Cir. 2017) .....	11
<i>Champaign-Urbana News Agency, Inc. v. J. L. Cummins News Co.</i> , 632 F.2d 680 (7th Cir. 1980) .....	12
<i>Choice Hotels Int'l, Inc. v. Patel</i> , 236 F. App'x 868 (4th Cir. 2007) .....	9, 10
<i>Christianson v. Colt Indus. Operating Corp.</i> , 486 U.S. 800 (1988).....	13
<i>City of Rancho Palos Verdes v. Abrams</i> , 544 U.S. 113 (2005).....	15
<i>Cordova v. Owens Corning Fiberglass Corp.</i> , 2002 WL 35649653 (D.N.M. Dec. 19, 2002).....	5
<i>County of Cuyahoga v. Purdue Pharma L.P.</i> , Case No. 17-OP-45004 (N.D. Ohio).....	3

<i>County of Summit v. Purdue Pharma L.P.</i> , Case No. 18-OP-45090 (N.D. Ohio).....	3
<i>Deutsch v. Novartis Pharm. Corp.</i> , 768 F. Supp. 2d 420 (E.D.N.Y. 2011) .....	6
<i>Everett v. Pitt Cty. Bd. of Educ.</i> , 788 F.3d 132 (4th Cir. 2015) .....	6
<i>Fenner v. Wyeth</i> , 912 F. Supp. 2d 795 (E.D. Mo. 2012).....	11
<i>In re Ford Motor Co.</i> , 591 F.3d 406 (5th Cir. 2009) .....	6, 12
<i>Gander Mountain Co. v. Cabela’s, Inc.</i> , 540 F.3d 827 (8th Cir. 2008) .....	10
<i>Gelboim v. Bank of Am. Corp.</i> , 135 S. Ct. 897 (2015).....	4
<i>GMAC Mortg., LLC v. McKeever</i> , 651 F. App’x 332 (6th Cir. 2016) .....	4, 10
<i>Gooch v. Life Inv’rs Ins. Co. of Am.</i> , 672 F.3d 402 (6th Cir. 2012) .....	10
<i>Harbor Ins. Co. v. Essman</i> , 918 F.2d 734 (8th Cir. 1990) .....	4
<i>In re Interest Rate Swaps Antitrust Litig.</i> , 351 F. Supp. 3d 698, 703 (S.D.N.Y. 2018).....	5
<i>In re Korean Air Lines Disaster</i> , 829 F.2d 1171 (D.C. Cir. 1987).....	5, 6, 13
<i>In re Life Invr’s Ins. Co.</i> , 589 F.3d 319 (6th Cir. 2009) .....	10
<i>In re Lipitor Antitrust Litig.</i> , 868 F.3d 231 (3d Cir. 2017).....	5
<i>Masters Pharmaceutical, Inc. v. DEA</i> , 861 F.3d 206 (D.C. Cir. 2017).....	20
<i>McCallister v. Purdue Pharma LP</i> , 164 F. Supp. 2d 783 (S.D. W.Va. 2011).....	15

<i>McKay v. Novartis Pharm. Corp.</i> , 751 F.3d 694 (5th Cir. 2014) .....	6
<i>McKesson Corp. et al. v. Hembree</i> , 2018 WL 340042 (N.D. Okla. Jan. 9, 2018).....	15
<i>Messinger v. Anderson</i> , 225 U.S. 436 (1912) .....	13
<i>In re Microsoft Corp. Antitrust Litig.</i> , 355 F.3d 322 (4th Cir. 2004) .....	3
<i>Montana v. United States</i> , 440 U.S. 147 (1979).....	9
<i>Morrison v. Nat'l Australia Bank Ltd.</i> , 561 U.S. 247 (2010) .....	18
<i>Nat'l City Golf Fin. v. Scott</i> , 899 F.3d 412 (5th Cir. 2018) .....	8
<i>In Re Nat'l Prescription Opiate Litig.</i> , 2019 WL 3917575 (N.D. Ohio Aug. 19, 2019).....	17
<i>Nw. Airlines, Inc. v. Transp. Workers Union of Am., AFL-CIO</i> , 451 U.S. 77 (1981).....	15
<i>Parkinson v. Novartis Pharm. Corp.</i> , 5 F. Supp. 3d 1265, 1271 (D. Or. 2014) .....	6
<i>Peralta v. Dillard</i> , 744 F.3d 1076 (9th Cir. 2014) .....	10, 13
<i>Perez-Ruiz v. Crespo-Guillen</i> , 25 F.3d 40 (1st Cir. 1994).....	11
<i>Pope v. Edward M. Rude Carrier Corp.</i> , 75 S.E.2d 584 (W. Va. 1953).....	14
<i>Reyes-Gaona v. N. Carolina Growers Ass'n</i> , 250 F.3d 861 (4th Cir. 2001) .....	18
<i>Rimbert v. Eli Lilly &amp; Co.</i> , 647 F.3d 1247 (10th Cir. 2011) .....	11
<i>Ross v. Blake</i> , 136 S. Ct. 1850 (2016).....	17

<i>Royster v. Food Lion, Inc.</i> , 73 F.3d 528 (4th Cir. 1996) .....	4, 7
<i>Sejman v. Warner-Lambert Co.</i> , 845 F.2d 66 (4th Cir. 1988) .....	1, 11
<i>Smith v. Hickenlooper</i> , 164 F. Supp. 3d 1286, 1290 (D. Colo. 2016).....	14
<i>U.S. ex rel. Staley v. Columbia/HCA Healthcare Corp.</i> , 587 F. Supp. 2d 757 (W.D. Va. 2008) .....	6
<i>State of West Virginia, et al. v. McKesson Corp.</i> , No. 2:17-03555 (S.D. W. Va. Feb. 15, 2018).....	14
<i>Stone v. INS</i> , 514 U.S. 386 (1995).....	17
<i>TFWS, Inc. v. Franchot</i> , 572 F.3d 186 (4th Cir. 2009) .....	3
<i>In re United States</i> , 733 F.2d 10 (2nd Cir. 1984).....	11
<i>United States v. Aramony</i> , 166 F.3d 655 (4th Cir. 1999) .....	3, 6
<i>United States v. Burroughs</i> , 810 F.3d 833 (D.C. Cir. 2016).....	4
<i>United States v. Certain Land Situated in Detroit</i> , 361 F.3d 305 (6th Cir. 2004) .....	8
<i>United States v. Hawley</i> , 919 F.3d 252 (4th Cir. 2019) .....	19
<i>United States v. Maybusher</i> , 735 F.2d 366 (9th Cir. 1984) .....	4
<i>United States v. Moser</i> , 266 U.S. 236 (1924).....	9
<i>United States v. U.S. Smelting Ref. &amp; Min. Co.</i> , 339 U.S. 186 (1950).....	10
<i>Winkler v. Eli Lilly &amp; Co.</i> , 101 F.3d 1196 (7th Cir. 1996) .....	6

## Statutes and Regulations

21 U.S.C. § 823 .....	14, 16, 20
21 U.S.C. § 876 .....	18
21 U.S.C. § 879 .....	18
21 U.S.C. § 880 .....	19
21 U.S.C. § 881 .....	19
21 U.S.C. § 958 .....	16
28 U.S.C. § 1407 .....	7
21 C.F.R. § 1301.01 .....	16
21 C.F.R. § 1301.34 .....	16
21 C.F.R. § 1301.71 .....	14, 16, 17
21 C.F.R. § 1301.72 .....	16
21 C.F.R. § 1301.74 .....	10, 17, 18, 19
28 C.F.R. § 0.100 .....	16
Federal Controlled Substance Act (“CSA”), 21 U.S.C. § 801 <i>et seq.</i> .....	<i>passim</i>
SUPPORT for Patients and Communities Act, Pub. L. No. 115-271, 132 Stat. 3894 (Oct. 24, 2018) .....	17

## Other Authorities

58 Am. Jur. 2d New Trial § 415 (Aug. 2019 update) .....	10
18B Charles Alan Wright & Arthur R. Miller, Federal Practice & Procedure (4th ed. Aug. 2019 update) .....	<i>passim</i>
1B James W. Moore et al., <i>Moore’s Federal Practice</i> § 134/20[4] (2d ed. 1993) .....	11
Joan Steinman, <i>Law of the Case: A Judicial Puzzle in Consolidated and Transferred Cases and in Multidistrict Litigation</i> , 135 U. Pa. L. Rev. 595, 700 (1987) .....	5, 6
<i>Masters Pharmaceuticals, Inc.</i> , 80 Fed. Reg. 55,418, 2015 WL 5320504 (DEA Sept. 15, 2015) .....	19, 20

Restatement (Second) of Judgments § 28–29 (June 2019 update) .....	9
<i>Southwood Pharmaceuticals, Inc.</i> , 72 Fed. Reg. 36,487, 2007 WL 1886484 (DEA July 3, 2007).....	20
Weigle, S.A., <i>The Judicial Panel on Multidistrict Litigation, Transferor Courts and Transferee Courts</i> , 78 F.R.D. 575 (1977).....	4
William B. Rubenstein, 6 <i>Newberg on Class Actions</i> § 18:47 (5th ed.).....	8



## INTRODUCTION

Plaintiffs have asserted that the Order issued by Judge Polster on August 19, 2019 in two different cases that were pending before him in the MDL proceedings (“the MDL Order”) should be law of the case in this case. But the MDL court did not enter any order in *this* case regarding the federal Controlled Substance Act or how it could relate to Plaintiffs’ allegations of harm and claim to relief against Defendants<sup>1</sup> under public nuisance law of West Virginia. Whatever orders the MDL court entered in *other* cases, such as the cases brought by two Ohio counties, are not law of the case in this case. The law of the case doctrine applies only when the order at issue was entered earlier in the *same* case. There is no MDL exception to that rule. In short, the MDL Order is not law of the case here because that Order was entered in *different* cases brought by *different* plaintiffs.

A ruling of a district court, including an MDL court, of course may be analyzed to determine whether it is persuasive to another district court adjudicating a different case, taking into account the extent of legal analysis, strength of reasoning, differences in claims, governing law, facts, and so on, but that analysis here demonstrates that the MDL Order Plaintiffs invoke is clearly erroneous. If adopted, it would cause manifest injustice and create reversible error. Indeed, even if the Order could somehow meet the requirements to constitute law of the case for this case, it is not binding because the law of the case doctrine, itself, recognizes that erroneous rulings need not be followed. *See Sejman v. Warner-Lambert Co.*, 845 F.2d 66, 68 (4th Cir. 1988) (law of the case is “not an inexorable command”).

The Court need not reach the merits of the MDL Order if it concludes, consistent with the case law discussed in Part A below, that the Order is not law of the case, but we address in Part B

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<sup>1</sup> AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation.

some of the fatal flaws in the merits of that Order as a further and independent reason why it should not be law of the case here. The MDL Order addressed an abstract argument by two Ohio county plaintiffs about the federal Controlled Substances Act (“CSA”) without anchoring it to any analysis of the elements of the legal claims for relief in that case, none of which those plaintiffs contended even involved a cause of action under the federal CSA. The MDL Order thus amounted to an advisory view on the meaning of certain provisions of the federal CSA and regulations based on a truncated reading that fundamentally misconstrued those provisions. The MDL court opined that provisions of the federal CSA and regulations impose various “duties” on manufacturers and distributors. That conclusion is wrong. Those provisions instead identify factors for the DEA to consider in determining whether to issue, suspend, or revoke a manufacturer or distributor’s federal registration, but they do not support imposition of state tort liability and they certainly establish no duty owed by Defendants to Plaintiffs. Particularly in these circumstances, blind adherence by one federal district court to the erroneous ruling of another federal district court in a different case would contravene the authority vested in federal district courts by Article III, would thwart the orderly development of federal law ensured by the structure of the federal court system, and would be inconsistent with the due process protections in an adjudication by a federal district court of the claims and defenses of the parties in the suit before it.

## **ARGUMENT**

### **THE MDL COURT’S ORDER THAT WAS ENTERED IN DIFFERENT CASES IS NOT BINDING IN THIS CASE.**

#### **A. The MDL Order Is Not Law of the Case Because It Was Entered in Different Cases Involving Different Plaintiffs Alleging Different Claims.**

1. A ruling by a district court in one case is not binding law of the case in a different district court case, and there is no exception for cases that were at one time part of an MDL.

The Order of the MDL court that Plaintiffs urge be adopted by this Court is not an order that was entered in this case. Rather, it was entered by the MDL in two different cases brought by other plaintiffs, both Ohio counties, which the MDL court labeled the “Track One Cases.”<sup>2</sup> That court, itself, recognized that those cases were different from this one. It explicitly noted that “the Track One cases” contained “common law causes of action in Ohio [that] are different than in other states,” and that the “*City of Huntington*” and “*Cabell County* case[s]” “encompass additional parties and issues” distinct from Track One. Ex. A at 1.

The Track One MDL Order regarding the CSA is not law of the case here. “The law of the case doctrine ‘posits that when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the *same case*.’” *TFWS, Inc. v. Franchot*, 572 F.3d 186, 191 (4th Cir. 2009) (emphasis added) (quoting *United States v. Aramony*, 166 F.3d 655, 661 (4th Cir. 1999)). The Fourth Circuit repeatedly has made clear that, to trigger law of the case doctrine, an earlier ruling must be “*in the same case*.” *In re Microsoft Corp. Antitrust Litig.*, 355 F.3d 322, 328 (4th Cir. 2004) (emphasis in original); *see also, e.g.*, 18B Charles Alan Wright & Arthur R. Miller, *Federal Practice & Procedure* § 4478 (4th ed. Aug. 2019 update) (hereinafter “Wright & Miller”) (“Law-of-the-case rules ... [apply] during the course of a single continuing lawsuit”).

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<sup>2</sup> There were initially “three ‘Track One’ cases, all of which were brought by plaintiffs located in the Northern District of Ohio.” Order re Track Two, *In re Nat’l Prescription Opiate Litig.*, No. 17-MDL-2804 (N.D. Ohio filed Dec. 31, 2018), ECF No. 1218 (attached as Ex. A). These cases were (1) *County of Summit, Ohio v. Purdue Pharma L.P.*, Case No. 18-OP-45090 (N.D. Ohio), (2) *County of Cuyahoga, Ohio v. Purdue Pharma L.P.*, Case No. 17-OP-45004 (N.D. Ohio), and (3) *City of Cleveland, Ohio v. AmerisourceBergen Drug Corp.*, Case No. 18-OP-45132 (N.D. Ohio). The third case, *City of Cleveland*, was initially included as a Track One case but was dropped from the bellwether trial.

The law of the case doctrine “do[es] not apply between separate actions.” Wright & Miller § 4478; *see, e.g., Harbor Ins. Co. v. Essman*, 918 F.2d 734, 738 (8th Cir. 1990) (holding that where the case *sub judice* is merely related to, but was not the “same case,” the law of the case doctrine does not apply); *United States v. Maybusher*, 735 F.2d 366, 370 (9th Cir. 1984) (“This matter is not entirely the same case ... [and accordingly the] doctrine does not apply in this matter.”); *United States v. Burroughs*, 810 F.3d 833, 838 (D.C. Cir. 2016) (“[Defendant] is seeking to bind the courts across different cases. [But] ... the law of the case doctrine only applies within the same case.”)

There is no exception for cases in an MDL. The Supreme Court has instructed that cases consolidated in an MDL do **not** merge into a single case (at least in the absence of a master consolidated complaint, which was not filed in the MDL at issue here); instead they “ordinarily retain their separate identities.” *Gelboim v. Bank of Am. Corp.*, 135 S. Ct. 897, 904 (2015); *accord* Wright & Miller § 3862 (same). It is a “well-established principle that consolidated cases remain separate actions” for purposes of law of the case doctrine; a ruling on an issue is binding law of the case only when “the **same** issue [is] presented a second time in the **same** case in the **same** court.” *GMAC Mortg., LLC v. McKeever*, 651 F. App’x 332, 339 (6th Cir. 2016) (emphases in original).

The Fourth Circuit’s decision in *Royster v. Food Lion, Inc.* is not to the contrary. That case involved prior rulings in the **same** cases. The MDL court already had entered “summary judgment orders in the cases remanded to the transferor courts” and appeals from those remanded cases were before the court of appeals when that court noted “[i]t would be improper to permit a transferor judge to overturn ... the rulings of the transferee judge ... [as otherwise] those proceedings would then lack the finality (at the trial court level) requisite to ... the efficient conduct of actions.” 73 F.3d 528, 531–32 (4th Cir. 1996) (quoting Weigle, S.A., *The Judicial Panel on Multidistrict*

*Litigation, Transferor Courts and Transferee Courts*, 78 F.R.D. 575, 577 (1977)). The Fourth Circuit did not address the argument Plaintiffs make here—namely, that an MDL ruling in one case should be law of the case in a *different* case.

Numerous courts have correctly and explicitly recognized that rulings by an MDL court in one case in an MDL are not binding law of the case in other cases in that MDL. *See, e.g., In re Lipitor Antitrust Litig.*, 868 F.3d 231, 268 n.18 (3d Cir. 2017) (error to rely on decision in separate MDL action by different plaintiffs as binding law of the case, a doctrine “that does not apply here because it only applies within a single litigation”); *In re Interest Rate Swaps Antitrust Litig.*, 351 F. Supp. 3d 698, 703 (S.D.N.Y. 2018) (“Although trueEX’s complaint has been consolidated with these earlier cases for pretrial supervision in this MDL, it is formally a separate case. The law of the case doctrine thus does not apply here.”); *Cordova v. Owens Corning Fiberglass Corp.*, 2002 WL 35649653, at \*3 (D.N.M. Dec. 19, 2002) (“Plaintiff is correct that the law of the case doctrine does not apply to Plaintiff’s claims which had been remanded to this Court” from an MDL court); *see also* Joan Steinman, *Law of the Case: A Judicial Puzzle in Consolidated and Transferred Cases and in Multidistrict Litigation*, 135 U. Pa. L. Rev. 595, 700 (1987) (“Remand courts should take care to utilize law of the case doctrine only when the ruling in question was made in the very case before the remand court, not exclusively in other components of the multidistrict litigation.”).

2. These clear limitations on the law of the case doctrine are rooted in the responsibility of Article III courts to develop the law and ensure due process by adjudicating the claims and defenses of the parties before them. In a prominent MDL action, then-Judge Ginsburg explained: “The federal courts spread across the country owe respect to each other’s efforts and should strive to avoid conflicts, but each has an obligation to engage independently in reasoned analysis. Binding precedent for all is set only by the Supreme Court, and for the district courts

within a circuit, only by the court of appeals for that circuit.” *In re Korean Air Lines Disaster*, 829 F.2d 1171, 1176 (D.C. Cir. 1987) (Ginsburg, J.).<sup>3</sup>

Plaintiffs cite no authority that calls into question the principle that a ruling cannot be law of the case unless it was entered in the *same* case. Instead, the case law Plaintiffs cite involves only circumstances where the earlier order *was* entered in the same case. *See* Br. 5–9.<sup>4</sup> The fact

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<sup>3</sup> *Korean Air* recognized that, to constitute law of the case, an order must have been entered in the same case. There, the D.C. Circuit accepted an interlocutory appeal from an order entered in multiple consolidated cases and affirmed the district court’s conclusion on the issue involved in those cases. *See id.* at 1173, 1176. The D.C. Circuit then indicated that “[s]hould the several cases ... in the instant proceeding eventually return to transferor courts ... [the issue on] which we have affirmed [should] have binding force ... as ‘law of the case.’” *Id.* at 1176 (citing Steinman, *supra*, at 664–67, 700–04). This indicated that final resolution by an appellate court of an issue in a case may become law of case during further proceedings in *that* case, but *not* in *different* cases.

<sup>4</sup> *See Everett v. Pitt Cty. Bd. of Educ.*, 788 F.3d 132, 142 (4th Cir. 2015) (“Once a court has established law of the case, it must be followed in all subsequent proceedings in the same case....” (quoting *United States v. Aramony*, 166 F.3d 655, 661 (4th Cir. 1999))); *McKay v. Novartis Pharm. Corp.*, 751 F.3d 694, 703 (5th Cir. 2014) (affirming district court’s rejection of “motion for reconsideration filed almost three years after the MDL court’s summary judgment ruling” in same case); *In re Ford Motor Co.*, 591 F.3d 406, 408 (5th Cir. 2009) (litigant “requested that the district court reconsider a pretrial ... motion that had been denied by [the] multidistrict litigation ... court” in the same case); *Winkler v. Eli Lilly & Co.*, 101 F.3d 1196, 1202 & n.5 (7th Cir. 1996) (noting, in dicta, that after remand parties cannot “simply re-visit the transferee court’s pre-trial rulings” in same case); *Amorin v. Taishan Gypsum Co., Ltd.*, 2019 WL 2172707, at \*1–2 (E.D. Va. May 20, 2019) (“default judgement was entered [by the MDL court] against Defendants [in the same case] many years ago, leaving the proper damages calculation as the only issue to be litigated”; moreover, remediation ruling at issue was issued in same case following MDL court’s classwide damages hearing, after which case was remanded “to allow for individualized damages calculations”); *U.S. ex rel. Staley v. Columbia/HCA Healthcare Corp.*, 587 F. Supp. 2d 757, 758 (W.D. Va. 2008) (“In this qui tam action remanded to this court for trial from a multidistrict litigation court, the relator seeks reconsideration of a decision of the transferee court that dismissed a portion of the qui tam claim”; law of the case doctrine “requires courts to uphold earlier decisions in the same case” (quotation omitted)); *Parkinson v. Novartis Pharm. Corp.*, 5 F. Supp. 3d 1265, 1271 (D. Or. 2014) (MDL court ruling “should continue to govern the same issues in subsequent stages in the same case” (quotation omitted)); *Deutsch v. Novartis Pharm. Corp.*, 768 F. Supp. 2d 420, 428 (E.D.N.Y. 2011) (“the MDL court [had] denied the *Daubert* motions ... that Novartis made [in same case] ... [and following remand] Novartis would have this Court review ... de novo”). Finally, the district court in *Adesina v. Aladan Corp.*, 438 F. Supp. 2d 329 (S.D.N.Y. 2006), did not consider itself bound by law of the case doctrine; it simply found the MDL court’s (continued...)

that some of the cases cited involve an MDL context is unremarkable. In those instances, the MDL court had issued the ruling in question in the specific case at issue and *that* case was “remanded by the panel [to the original transferor court] ... at ... the conclusion of ... pretrial proceedings.” 28 U.S.C. § 1407(a).<sup>5</sup> Here, by contrast, this case was remanded “before the conclusion of pretrial proceedings,” *id.*, and after only a limited number of orders were entered by the MDL court in this particular case.<sup>6</sup>

Contrary to what Plaintiffs contend (at Br. 2, 6), the Manual for Complex Litigation (Fourth) § 20.133 does not support their argument. The passage they cite explains that “[a]fter remand, ... [as the] transferor court conducts further pretrial proceedings ... the transferor judge has the power to vacate or modify rulings made by the [MDL] judge, subject to comity and ‘law of the case’ considerations.” *Id.* That passage plainly does not say that orders entered by the MDL court in one case are law of the case in different cases. Instead, when read in context, the Manual’s discussion necessarily relates to rulings that had been issued by an MDL judge in the case that was subsequently remanded. The full excerpt from *Newberg on Class Actions* (quoted only in part by Plaintiffs at Br. 6) is to similar effect because it reflects the same principle that “the law of the case doctrine posits that when a court decides upon a rule of law, that decision should continue to govern

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ruling on an issue persuasive. *See id.* at 348 (court could find “no reason to deviate from [the MDL judge’s] *Daubert* findings” as to specific witness).

<sup>5</sup> The remand of a case (like this one) at its infancy is a permissible, albeit atypical, means of proceeding for an MDL. *Cf. Royster*, 73 F.3d at 532 (“In practice ..., the vast majority of transferred cases are disposed of completely in the [MDL] court, either through pretrial dispositions such as summary judgment, or by trial.”).

<sup>6</sup> The orders entered by the MDL court in this case were largely ministerial and included decisions allowing Plaintiffs to file amended complaints (MDL Dkts. Nos. 257, 516); granting a motion to take judicial notice of certain documents (MDL Dkt. No. 679); and granting Plaintiffs’ motion to sever other defendants aside from the Defendants here and to voluntarily dismiss all claims except public nuisance under West Virginia law (MDL Dkt. 2990).



the same issues in subsequent stages *in the same case*.” William B. Rubenstein, 6 *Newberg on Class Actions* § 18:47 (5th ed.) (emphasis added and quotation omitted).

Plaintiffs also err (at Br. 10) in relying on a different MDL court Order that purported to make evidentiary rulings *nunc pro tunc* on motions *in limine* filed by two plaintiff Ohio counties. That order included dicta by the MDL court that purported to control cases to be remanded and tried by transferor courts. *See* Certain Defs. Notice of Position at 2, *In re Nat’l Prescription Opiate Litig.*, No. 1:17-md-02802 (N.D. Ohio filed Jan. 31, 2020), ECF No. 3133 (attached as Ex. B). There are two problems with this *nunc pro tunc* order and Plaintiffs’ reliance on it. First, that Order has no force or effect because the MDL court lacked jurisdiction to enter it. Months before that Order was entered, the court had dismissed with prejudice the claims by the plaintiffs that had filed the motions, as a result of the parties’ settlement. Various Track One defendants, including the Defendants here, filed a notice with the Court identifying that fatal jurisdictional flaw. *See id.* at 3; *see also Nat’l City Golf Fin. v. Scott*, 899 F.3d 412, 415–16 (5th Cir. 2018) (“A stipulation of dismissal ... ordinarily—and automatically—strips the district court of subject-matter jurisdiction.”). The lack of jurisdiction and the fact the case had been dismissed also meant that Defendants could not appeal that Order. *See United States v. Certain Land Situated in Detroit*, 361 F.3d 305, 307 (6th Cir. 2004) (“We lack appellate jurisdiction where the district court lacked subject matter jurisdiction.”).

Second, those purported interlocutory evidentiary rulings about the admissibility of certain evidence—in advance of a trial on common-law claims under Ohio law and federal RICO—certainly would have no binding effect in this case involving a public nuisance claim brought under the law of a different State and where Plaintiffs’ alleged injuries involve different facts and circumstances relevant to a West Virginia city and county. Plaintiffs’ effort (Br. at 9) to rely on a



transcript from a status conference in a recently remanded case in another jurisdiction is similarly misplaced because of the different circumstances and absence of any briefing on the issue.

3. Plaintiffs assert that it would be “especially inappropriate” for this Court to disagree with the MDL court’s rulings on “pure legal questions of federal law.” Br. 2. But the opposite is true—it would be especially inappropriate under settled law for this Court to follow the MDL Court’s opinion on the CSA, which was, at best, an advisory and purely legal opinion on certain provisions of federal law in a case where the plaintiffs’ claims were *not* brought under any cause of action in the CSA, but rather consisted of a federal RICO claim and common-law claims under Ohio law, all of which are distinct from the public nuisance claim controlled by West Virginia law in this case.

Federal courts broadly recognize that opinions on pure questions of law—*i.e.*, “principles of law formulated in abstract terms that could apply to completely separate fact settings”—are not susceptible to doctrines such as collateral estoppel and res judicata, Wright & Miller § 4425, which are viewed as “kindred” to “the law of the case” doctrine for such purposes. *Choice Hotels Int’l, Inc. v. Patel*, 236 F. App’x 868, 870 (4th Cir. 2007); *see also, e.g., Montana v. United States*, 440 U.S. 147, 162–63 (1979) (“[T]he doctrine of *res judicata* ... [usually] does not apply to unmixed questions of law.” (quoting *United States v. Moser*, 266 U.S. 236, 242 (1924))); Restatement (Second) of Judgments § 28–29 (June 2019 update) (similar). Courts, therefore, are not forced to adhere to a purely legal determination because “[t]he interests of courts and litigants alike can be protected adequately by the flexibility of stare decisis,” *i.e.*, the normal rules by which courts look at other decisions as either potentially persuasive or precedential depending on their relative position within the federal system. Wright & Miller § 4425. A court looking at a purely legal

ruling should not be “foreclosed from an opportunity to reconsider the applicable rule, and thus to perform its function of developing the law.” Restatement (Second) at § 29 cmt. i.

4. The MDL court’s opinion on the CSA was not law of the case even in the Track One cases involving the Ohio counties. Typically, an order is not binding law of the case unless it was necessary to a final judgment, and not merely an interlocutory order. The Supreme Court, Fourth Circuit, and numerous other courts have recognized that “the law of the case does not apply unless there is a final judgment that decided the issue.” 58 Am. Jur. 2d New Trial § 415 (Aug. 2019 update); see *United States v. U.S. Smelting Ref. & Min. Co.*, 339 U.S. 186, 199 (1950) (“[I]t requires a final judgment to sustain the application of the rule of the law of the case ....”); *Choice Hotels*, 236 F. App’x at 870 (“[I]t requires a final judgment to sustain the application of the rule of the law of the case just as it does for the kindred rule of *res judicata*.”).<sup>7</sup> The MDL court’s opinion on the federal CSA was a partial summary judgment adjudication, see Br. 4 n.1, which is an interlocutory order, not a final judgment. See *Am. Canoe Ass’n v. Murphy Farms, Inc.*, 326 F.3d 505, 514 (4th Cir. 2003). It could have been modified by that court before final judgment. See *id.* at 514–15 (“district court retains the power to reconsider and modify its interlocutory judgments, including partial summary judgments”); see also, e.g., *Gooch v. Life Inv’rs Ins. Co. of Am.*, 672 F.3d 402, 412, 433 (6th Cir. 2012) (“law-of-the-case doctrine” does not apply to “grant of partial summary judgment”; there “[i]s ultimately nothing legally stopping the court from

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<sup>7</sup> See also, e.g., *Askins v. U.S. Dep’t of Homeland Sec.*, 899 F.3d 1035, 1042 (9th Cir. 2018) (error for district court to invoke law of the case when it “did not enter a final judgment in the case”); *GMAC*, 651 F. App’x at 338-39 (“law-of-the-case is designed to prevent the relitigation of an issue once there has been a judgment on the merits”); *In re Life Invr’s Ins. Co.*, 589 F.3d 319, 326 n.6 (6th Cir. 2009) (“‘law of the case’ doctrine does not apply [to interlocutory decisions], as a district court may always reconsider and revise [such] orders....”); *Gander Mountain Co. v. Cabela’s, Inc.*, 540 F.3d 827, 830 (8th Cir. 2008) (“[t]he doctrine does not apply to interlocutory orders”).

(continued...)

revisiting the issue”); *Peralta v. Dillard*, 744 F.3d 1076, 1088 (9th Cir. 2014) (en banc) (“denial of a summary judgment motion is never law of the case”); *Perez-Ruiz v. Crespo-Guillen*, 25 F.3d 40, 42 (1st Cir. 1994) (“Interlocutory orders, including denials of motions to dismiss, remain open to trial court reconsideration, and do not constitute the law of the case.”).<sup>8</sup>

Although the Fourth Circuit has noted that a transferor court “should be hesitant to overrule [an] earlier determination” of an MDL court, *Carlson v. Bos. Sci. Corp.*, 856 F.3d 320, 325 (4th Cir. 2017), that was in the context of an interlocutory order entered in the *same* case. Accordingly, *Carlson* does not support Plaintiffs’ arguments here for the reasons set forth above.<sup>9</sup> Moreover, the Fourth Circuit specifically noted that the transferor court should be guided by circumstances that would allow overruling even under the law of the case doctrine. Confirming that law of the case is “not an inexorable command,” *Sejman*, 845 F.2d at 68, *Carlson* recognized that even when an MDL court enters an order in the *same* case, the transferor court “may [still] revise” that order on remand when, *inter alia*, there is clear error that would cause manifest injustice, 856 F.3d at 325.

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<sup>8</sup> The interlocutory nature of the MDL opinion on the CSA is further underscored by the fact that the losing party was unable to seek appellate review, contrary to the purpose of the law of the case doctrine. See *Burks v. O'Connor, Kenny Partners, Inc.*, 77 F. App’x 351, 355 n.3 (6th Cir. 2003) (law of the case “applies in interlocutory appeals only to matters that have actually been decided” by the appellate tribunal (quoting 1B James W. Moore et al., *Moore’s Federal Practice* § 134/20[4] (2d ed. 1993))).

<sup>9</sup> Numerous other courts recognize that law of the case does not apply to interlocutory orders even when a case is transferred to another court. See, e.g., *Rimbert v. Eli Lilly & Co.*, 647 F.3d 1247, 1252 (10th Cir. 2011) (“law of the case doctrine has no bearing on the revisiting of interlocutory orders, even when a case has been reassigned from one judge to another”); *In re United States*, 733 F.2d 10 (2nd Cir. 1984) (rule against interlocutory orders being binding applies “to the same extent if the case is reassigned to another judge”); *Allen v. Am. Capital Ltd.*, 287 F. Supp. 3d 763 (D. Ariz. 2017) (“the law-of-the-case doctrine likely does not bind this [transferor] Court to follow pretrial rulings [of the MDL court]; therefore, it can discretionarily reconsider the motion for summary judgment with no further analysis.”); *Fenner v. Wyeth*, 912 F. Supp. 2d 795, 799 (E.D. Mo. 2012) (“law-of-the-case doctrine does not apply to the MDL court’s rulings” where ruling was interlocutory order).

As demonstrated in the next section, the MDL court's advisory views on the federal CSA are clearly erroneous and would cause manifest injustice, and so should not be followed. *See, e.g., In re Ford Motor Co.*, 591 F.3d at 412 (issuing writ of mandamus because "the transferor court should have recognized [the MDL court's] serious error," which was "so clearly erroneous that it would work a manifest injustice" and required departure from law of the case doctrine); *see also In re Airport Car Rental Antitrust Litig.*, 521 F. Supp. 568, 572 (N.D. Cal. 1981) ("The law of the case is not entitled to the same respect as the doctrine of *stare decisis*. The law of the case does not demand obsequiousness right or wrong. ... The only sensible thing for a trial court to do is to set itself right as soon as possible when convinced that the law of the case is erroneous" (quoting *Champaign-Urbana News Agency, Inc. v. J. L. Cummins News Co.*, 632 F.2d 680, 683 (7th Cir. 1980)), *aff'd*, 693 F.2d 84 (9th Cir. 1982).

**B. Law of the Case Does Not Support Adoption of the MDL Order Because That Order Is Clearly Erroneous and Would Cause Manifest Injustice.**

The Court need not reach the merits of the MDL Order regarding the federal CSA if it concludes, consistent with the case law discussed in Part A, that the Order is not law of the case. At this stage of the litigation, that is the only question to be resolved, and it is premature and unnecessary to reach the merits of the reasoning of the MDL Order. No motions are before the Court that frame up the substantive issues addressed in the MDL Order. However, the reasoning of the MDL Order is a further, independent basis why it should not be binding as law of the case—because the MDL Order is clearly erroneous and its adoption here would cause manifest injustice and would give rise to reversible error. We address these points in this section as a further and independent reason why the MDL Order should not be law of the case in this case. If Plaintiffs wish to press their mistaken argument that the federal CSA creates duties, they need to file a motion for partial summary judgment that attempts to make that argument on its supposed merits, and

Defendants will respond. What Plaintiffs plainly may not do is bootstrap the MDL Order into this case through deeply flawed reliance on the law of the case doctrine.

“[T]he law-of-the-case doctrine ‘merely expresses the practice of courts generally to refuse to reopen what has been decided, [and is] not a limit to their power.’” *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 817 (1988) (quoting *Messinger v. Anderson*, 225 U.S. 436, 444 (1912) (Holmes, J.))

A ruling of another district court, may, of course, be analyzed to determine whether it is persuasive to another district court adjudicating a different case, taking into account the extent of legal analysis, strength of reasoning, differences in claims, governing law, facts, and so on. That analysis here demonstrates that the MDL opinion on the CSA that Plaintiffs urge be adopted by this Court has no persuasive force; indeed, that opinion is clearly erroneous and should not be followed by this court to avoid manifest injustice and reversible error. “There is no room in the federal system for rote acceptance of the decision of a court outside the chain of direct review. If a federal court simply accepts the interpretation of another [court] without [independently] addressing the merits, it is not doing its job.” *In re Korean Air Lines Disaster*, 829 F.2d. at 1175 (Ginsburg, J.). “It makes no sense to say that ... if a district court realizes a ... ruling was mistaken, it can’t correct it, but must instead wait to be reversed on appeal.” *Peralta*, 744 F.3d at 1088.

1. The MDL opinion addressed an argument by the plaintiffs there (two Ohio counties) regarding the federal CSA and implementing regulations, even though the plaintiffs maintained that they were not seeking relief under those laws. The plaintiffs there nonetheless sought the views of the court on an abstract notion of “duties” under those laws so that those plaintiffs could then attempt to rely on them to try to seek relief under other laws. As a threshold matter, the determination of such abstract “duties” apart from the source of any law that would

support the plaintiffs' claim to relief in that case was inappropriate. Moreover, the MDL court fundamentally misconstrued the nature of the federal CSA provisions.

The MDL court opined that the federal CSA and implementing regulations impose certain "duties" on manufactures and distributors. But those federal law provisions only identify factors for DEA's consideration in determining whether to issue, suspend, or revoke a manufacturer or distributor's federal registration, including consideration of whether the registrant has substantially complied with various regulatory provisions. *See* 21 U.S.C. § 823(a)–(b), (d)–(e); 21 C.F.R. § 1301.71(a)–(b). That registration scheme is enforced exclusively by the DEA, and does not proscribe particular conduct or authorize civil or criminal penalties for the conduct Plaintiffs allege here. Nor does it support state tort liability, and certainly imposes no "duties" owed by Defendants to a county or city, like the Plaintiffs here.

Plaintiffs allege that Defendants' purported regulatory noncompliance can nonetheless serve as a violation of law antecedent to establishing liability for nuisance under West Virginia common law. *See* Third Am. Compl. ¶ 1421. But an act that is "lawful, or is authorized by a valid statute, or which the public convenience imperatively demands, cannot be a public nuisance." *Pope v. Edward M. Rude Carrier Corp.*, 75 S.E.2d 584, 589 (W. Va. 1953). Here, the federal CSA and regulatory registration provisions are factors for DEA to consider when making registration determinations. They are not legal proscriptions or duties owed to Plaintiffs that render the alleged actions of Defendants unlawful. Indeed, the DEA has consistently renewed the Defendants' registrations to distribute controlled substances in West Virginia.

Moreover, "federal courts have uniformly held that the [federal] CSA does not create a private right of action." *Smith v. Hickenlooper*, 164 F. Supp. 3d 1286, 1290 (D. Colo. 2016); *see also State of West Virginia, et al. v. McKesson Corp.*, No. 2:17-03555 (S.D. W. Va. Feb. 15, 2018)

(ECF No. 21), at 14-15; *McKesson Corp. et al. v. Hembree*, 2018 WL 340042, at \*5 (N.D. Okla. Jan. 9, 2018). The DEA’s registration factors do not create—and cannot be relied upon to create—a legal duty owed to the general public or state government or private entities for purposes of a public nuisance claim. *See McCallister v. Purdue Pharma LP*, 164 F. Supp. 2d 783, 793 & n. 16 (S.D. W.Va. 2011) (finding “no Congressional intent to create a private, civil right of action” for claims under the CSA and no “indication of legislative intent” to create an implicit private remedy); *Nw. Airlines, Inc. v. Transp. Workers Union of Am., AFL-CIO*, 451 U.S. 77, 97 (1981) (“The judiciary may not, in the face of such comprehensive legislative schemes, fashion new remedies that might upset carefully considered legislative programs.”). And the Supreme Court has instructed that a state law cause of action may not be used to *indirectly* enforce a federal statute where Congress has not authorized private enforcement. *See, e.g., Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011) (private party cannot indirectly enforce § 340(B) of the Public Health Services Act, 42 U.S.C. § 256(b), through breach of contract claim); *City of Rancho Palos Verdes v. Abrams*, 544 U.S. 113, 119–20 (2005).

An attempt to create state law liability based on the federal CSA in these circumstances would raise serious questions of preemption by federal law. Allowing indirect private enforcement of the CSA through state law tort claims would frustrate Congress’ intent and contravene its judgments about how the CSA should be enforced. *See Astra*, 563 U.S. at 120 (“Far from assisting” the administrative agency, private suits “would undermine the agency’s efforts to administer” the statute, by spawning “a multitude of dispersed and uncoordinated lawsuits.”).

2. The MDL court’s opinion is contrary to the plain text of the federal CSA and regulatory provisions.

The federal CSA provides that, in order to distribute a Schedule I or II controlled substance for lawful purposes, a wholesale distributor must apply for a registration with DEA and renew annually. *See* 21 U.S.C. § 958(a); 21 C.F.R. § 1301.34(b); 28 C.F.R. § 0.100(b). Congress has directed that DEA “shall register an applicant” unless it determines “that the issuance of such registration is inconsistent with the public interest.” 21 U.S.C. § 823(b). “In determining the public interest” for purposes of registration, revocation, or suspension, the statute instructs DEA to consider certain factors, including the applicant’s “maintenance of effective controls against diversion.” 21 U.S.C. § 823, 824(a)(4). The implementing regulations address the “[p]rocedures governing the registration” of distributors, 21 C.F.R. § 1301.01, and indicate that registrants “shall provide effective controls and procedures to guard against theft and diversion of controlled substances,” 21 C.F.R. § 1301.71(a). The next sentence states that, “[i]n order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in §§ 1301.72–1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion.” 21 C.F.R. § 1301.71(a). The regulations specify that “[s]ubstantial compliance with the standards set forth in §§ 1301.72–1301.76 may be deemed sufficient” by the agency “after evaluation of the overall security system.” 21 C.F.R. § 1301.71(b). Any revocation requires enforcement proceedings with due process protections. 21 U.S.C. § 824(c).

The standards set forth in §§ 1301.72 to 1301.76 largely address physical handling of controlled substances, including specifications for storage areas, cabinets, vaults, cages, alarms, compounding areas, and the like. *See, e.g.*, 21 C.F.R. § 1301.72. These provisions focus on the time when controlled substances are stored or handled by a registrant in its own segment of the



supply chain, and vests the agency with discretion to consider those factors in its administrative reviews of whether an entity's continued federal registration is consistent with the public interest.

The standards also include a provision relating to identifying and informing DEA of “suspicious orders.” 21 C.F.R. § 1301.74(b). The regulations provide that, as part of the federal CSA registration scheme's effective controls provisions, registrants shall (i) “design and operate a system to disclose to the registrant suspicious orders of controlled substances,” and (ii) “inform” DEA “of suspicious orders when discovered.” *Id.* § 1301.74(b). The regulations define suspicious orders as those of “unusual size,” “unusual frequency,” or “deviating substantially from a normal pattern.” 21 C.F.R. § 301.74(b). As with other “security requirements set forth in §§ 1301.72–1301.76,” 21 C.F.R. § 1301.71(a), substantial compliance is sufficient for maintaining registration, and there is nothing in federal law indicating that a registrant's failure to substantially comply with these provisions gives rise to any obligation running to or enforceable by Plaintiffs here.<sup>10</sup> Therefore, those registration provisions cannot give rise to independently actionable and binding legal “duties.”

3. The MDL court also erred as a matter of law when it rewrote the CSA to create a no-shipping requirement that does not appear anywhere in the text of the CSA or regulations. The MDL court acknowledged that the text did not embody any such requirement, but it nevertheless implied a no-shipping requirement based on its own view of what Congress and the agency should

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<sup>10</sup> In 2018, the federal CSA was amended to authorize DEA to impose civil fines for failures to substantially comply with certain registration provisions. *See* Pub. L. No. 115-271, 132 Stat. 3894, 3953 (Oct. 24, 2018). That amendment confirms that even such a fine was not authorized before 2018. *See Ross v. Blake*, 136 S. Ct. 1850, 1858 (2016) (“When Congress amends legislation, courts must ‘presume it intends [the change] to have real and substantial effect.’” (quoting *Stone v. INS*, 514 U.S. 386, 397 (1995))). In this case, Plaintiffs' factual allegations concern purported conduct occurring from 2001 to 2016, *see, e.g.*, Third Am. Compl. ¶ 31 (alleging sales in Cabell County “[f]rom 2006 to 2014”).

have done. The court stated it was “hard-pressed to think of a more basic requirement than not to ship a dubious order bearing indicia that the drugs could be diverted to illegal channels.” *In Re Nat’l Prescription Opiate Litig.*, 2019 WL 3917575, at \*9 (N.D. Ohio Aug. 19, 2019). One may “think of” many measures Congress and DEA might have enacted to regulate prescription opioids in various ways, but such “thoughts” cannot create requirements that are absent from the text of the duly enacted and promulgated statutes and regulations. *See Morrison v. Nat’l Australia Bank Ltd.*, 561 U.S. 247, 270 (2010) (Scalia, J.) (“It is our function to give the statute the effect its language suggests, however modest that may be; not to extend it to admirable purposes it might be used to achieve.”).

Examination of further details in the text and structure of the federal law and neighboring provisions confirms the clear error of the MDL court’s atextual creation of a duty not to ship suspicious orders. First, 21 C.F.R. § 1301.74(b) details the actions that registrants are to take regarding suspicious orders, providing that they shall (i) “design and operate a system to disclose to the registrant suspicious orders of controlled substances” and (ii) “inform” DEA “of suspicious orders when discovered by the registrant.” 21 C.F.R. § 1301.74(b). There is no provision against shipping suspicious orders. *See Reyes-Gaona v. N. Carolina Growers Ass’n*, 250 F.3d 861, 865 (4th Cir. 2001) (“*expressio unius est exclusio alterius* instructs that where a law expressly describes a particular situation to which it shall apply, what was omitted or excluded was intended to be omitted or excluded.”).

Requiring registrants to identify and inform DEA of suspicious orders, without imposing a requirement that registrants not ship such orders, is wholly consistent with the law enforcement authority Congress vested in DEA, including the much greater information and data that DEA has from all manufacturers, distributors, and pharmacies across the country. DEA is specifically

vested with investigative tools and prosecutorial discretion to enforce the federal regulatory scheme through official agency regulations and actions, within the confines of the statute. That authority includes subpoena power, 21 U.S.C. § 876, specific search warrant authority, 21 U.S.C. § 879, inspection authority, 21 U.S.C. § 880, forfeiture authority 21 U.S.C. § 881, and other powers, including broad access to detailed data from a wide range of businesses in all segments of the prescription pharmaceutical supply chain. And it is for DEA, in carrying out that authority, to account for the other interests it is charged by law with furthering, including avoiding undue disruption in the supply chain for medicines critical to the public safety and health of individuals throughout the country.

Second, the regulations elsewhere impose a no-shipping requirement in limited circumstances, confirming that such a requirement could have been, but was not, included for suspicious orders. The regulations state that a registrant “shall not distribute any controlled substance listed in Schedules II through V as a complimentary sample to any potential or current customer” unless certain conditions are satisfied. 21 C.F.R. §1301.74(d). The absence of a comparable provision relating to suspicious orders is fatal to the MDL court’s opinion that a “no ship” requirement exists that is not provided for in the statute or regulations. *See United States v. Hawley*, 919 F.3d 252, 256 (4th Cir. 2019) (describing *expressio unius* canon).

4. Having no statutory or regulatory text to support their “duties” theory, Plaintiffs invoke two agency adjudications cited by the MDL court, but those agency revocations of registrations for specific entities do not govern Defendants here. Under basic principles of administrative law, they are not binding on entities not party to the adjudication, who would have due process protections through an individualized administrative process before revocation actions could be taken against them. DEA, itself, has explained that when a “rule [i]s announced in an

adjudication”—rather than through notice-and-comment rulemaking—an entity is, “of course, free to argue why the rule should not be applied” in a future administrative action. *See Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55,418, 55,476, 2015 WL 5320504 (DEA Sept. 15, 2015).

And, in any event, those adjudications did not purport to impose a no-shipping-suspicious-orders requirement on registrants generally. In *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487, 2007 WL 1886484 (DEA July 3, 2007), DEA had advised the company that DEA “cannot tell a distributor whether a particular order is legitimate or not” and that instructing the company that “whether to ship was ‘a business decision.’” *Id.* at 36,493. DEA faulted that distributor for supplying controlled substances to Internet pharmacies that filled unlawful prescriptions issued by physicians without a legitimate doctor-patient relationship. *Id.* at 36,488 n.2. Then, DEA determined that statutory factors (maintenance of effective controls, past distribution experience, and public health and safety) supported its conclusion that continued registration of the company would be “inconsistent with the public interest.” *Id.* at 36,502–36,504 (citing 21 U.S.C. § 823(d)).

Similarly, in *Masters Pharmaceuticals*, DEA did not establish a requirement that suspicious orders not be shipped; indeed it expressly rejected the conflating of the shipping issue with the issue of when the DEA must be informed of suspicious orders. *See Masters Pharm.*, 80 Fed. Reg. at 55,478. And the D.C. Circuit, reviewing the *Masters* adjudication, explained that “even if the Administrator” had “impermissibly amended” its regulations to add a requirement not to ship suspicious orders, “that reading had no effect on his ultimate decision, and so provides no basis for relief.” *Masters Pharmaceutical, Inc. v. DEA*, 861 F.3d 206, 222 (D.C. Cir. 2017).

### CONCLUSION

For the foregoing reasons, this Court should deny Plaintiffs’ Motion to Adopt the MDL Court’s August 19, 2019 Order regarding the federal Controlled Substances Act.

Dated: March 17, 2020

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

The undersigned counsel hereby certifies that on this 17th day of March, the foregoing **“Memorandum Of Law In Opposition To Plaintiffs’ Motion To Adopt MDL Court’s August 19, 2019, Order Regarding The Federal Controlled Substances Act That Was Entered In Different Cases”** was served using the Court’s CM/ECF system, which will send notification of such filing to all counsel of record.

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